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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,680	01/25/2002	Teddy Kosoglou	CV01492K	9993

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
09/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/056,680	**Applicant(s)** KOSOGLOU ET AL.	
	Examiner San-ming Hui	**Art Unit** 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *25 July 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/San-ming Hui/
Primary Examiner, Art Unit 1617

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments filed April 23, 2008 averring the cited prior art's failure to teach or provide suggestions or motivation to ocmbine the teachings have been considered, but are not found persuasive. Applicant specifically argues that the herein claimed actives were taught in the cited prior art as different function. The exmaienr notes that all of the actives as claimed herein are taught in the cited priora rt as useful in reducing the risk of atherosclerosis, although they achieve that through different mechanisms of action. Examiner notes that the basis to combine is not based on the agents having same mechanism of action. The basis is rather they are known to have the same therapeutical use in the art. Therefore, possessing the teachings of the cited prior art, oen of ordinasy skill in the art would therefore combine these actives, which are known to be useful individually in reducing the risk of atherosclerosis, into a composition or method for the very same purpose, i.e., reducing the risk of atherosclerosis (See In re Kerkhoven 205 USPQ 1069 (CCPA 1980)).
Applicant's arguments averring the present of the unexpected benefits have been considered, but are not found persuaisve. Th examiner notes that the arguments is essentially addressed in the previous office actions. Although the unexpected result is demonstrated, the dosage claimed is not commensurate with the dosage used in the experiment. There is only one single dosage used for aspirin and one dosage for ezetimibe and yet the claims recite a very large range of both agents. It is not clear how one single dosage can extrapolate to a vast range of active. There is no rationale as to how the dosage of ezetimibe be expanded to a broad range as claimed. The rationale for expanding the dosage of aspirin is not convincing. For example, various references were cited in attempt to provide reasoning for the range of dosage recited in the claims; however, the herein claimed dosage range is not the normal dosage range for antiplatelet activity. Moreover, it is clear that different patient populations would need different dosages of aspirin. It is also true for different rat models. Killackey et al. reported that 200mg/kg of aspirin would be required to prevent carotid artery thrombosis and that 100mg/kg is insufficient. Therefore, one of ordinary skill in the art would see that the dosages of aspirin would be depending on what patient populations are being treated. In the instant case, only one rat model, one dosage of aspirin, and one dosage of ezetimibe were used. One cannot just simply extrapolate the dosage from one dosage point to a wide range based on what is generally known because what is shown is unexpected result. The dosage recited in the claims should be corresponding to the unexpected benefit of antiplatelet activities used demonstrated in Dr. Davis' declaration filed November 5, 2005. Accordingly, the claims are still considered properly rejected under 35 USC 103(a).